Application No. 10/659,063
Filed: September 10, 2003
TC Art Unit: 1623
Confirmation No.: 3827

REMARKS

This application has been subjected to a restriction requirement, and the Applicants confirm the election of the claims of Group I, claims 1-8, for prosecution at this time.

Claims 1-8 have been rejected under 35 USC § 112 and also under §§ 102 and 103 as either anticipated by or obvious over Pero et al. These rejections are respectfully traversed for the reasons given below and reconsideration is requested.

Applicants' cancellation and/or amendment of certain rejected claims is not to be construed as an admission that the Examiner's rejections were proper. The Applicants continue to believe that the rejected claims are described in and enabled by the specification, and are not obvious in view of the cited references. The rejected claims have been cancelled for the sole purpose of advancing the case to allowance. The Applicants reserve the right to file a continuing application to continue the prosecution of the rejected claims.

Rejection for lack of enablement

Claims 1-8 were rejected as not enabled by the specification, the Examiner stating that "[t]he treatment or prophylaxis (or prevention) of inflammatory conditions is not enabled since the

said inflammatory conditions does [sic] not have a single recognized cause." With respect, the Applicants point out to the Examiner that there can be many approaches to treating ailments or disorders that have an inflammatory response as one of their symptoms. Some scientists look for the underlying causes of an ailment or a disorder and try to find ways to prevent that condition from happening. Others look for ways to relieve the *symptoms* of the ailment or disorder. The inventors have taken the latter approach and discovered a mechanism of action of *inflammation*, which is a *symptom* of *many* ailments and disorders.

As described in the specification at p. 6, line 23 to p. 7, line 7, extracellular NAD^+, appears to be converted to cADPR, which enters immunostimulated cells and acts as a signalling molecule, being capable of "ameliorating structural and functional changes in cells affected by a proinflammatory milieu," (p. 7, lines 20-22). Thus, the inventors determined that inflammation, this *symptom* of many different ailments and disorders, can be treated by "administering to [a] patient a therapeutically effective amount of a composition comprising cyclic adenosine diphosphate ribose (cADPR), or a functional analogue or derivative thereof, . . ." as recited in amended claim 1.

Thus, Applicants submit that they have enabled one of ordinary skill to practice the method of the invention *as it is claimed*. The claimed method provides a way to treat a specific symptom of an ailment or disorder without having to know the underlying etiology of the patient's condition. Therefore, to practice the method of the invention, all one of ordinary skill has to know is that an inflammatory response has been triggered, which can be determined by observation of the patient without even knowing the cause of the inflammation.

The Examiner states further that the specification provides insufficient guidance with regard to these issues and provides no working examples. The Applicants point out to the Examiner that, in regard to the issue of working examples, a patent application as filed constitutes constructive reduction to practice. Applicants submit that if the methods as described would have been believable to those of ordinary skill, then actual working examples, complete with data, are not required. The Applicants have provides substantial teaching as to how the invention should be practiced. For example, as cADPR can be considered substantially like a nucleotide but without its base portion, the Applicants have looked to the extensive investigations carried out in recent years to identify oligonucleotide analogues and have

described, beginning at p. 9, line 24, the various ways that analogues or derivatives of cADPR (e.g., those that would be more stable *in vivo*) can be selected and identified. Starting at p. 10. line 26, specific methods of administration are described, and at p. 11, lines 7-10, a citation is given to exemplary methods for providing the compounds used in the method of the invention in drug form.

Thus, Applicants submit that the claimed method is fully enabled by the description in the specification and the rejection for lack of enablement is overcome.

Rejection for indefiniteness

The Examiner has rejected the pending claims saying that the recited analogues are indefinite. As mentioned above, the Applicants have included an extensive section in the specification (see p. 9, line 24 to p. 10, line 25) devoted to the description of specific analogues, which descriptions are fully referenced in the literature. Applicants submit that the meanings of all of the terms questioned by the Examiner are well known in the art and can be definitely determined by a practitioner of the claimed method by looking at the specifically cited reference. Thus, Applicants believe that the rejection for indefiniteness has been overcome.

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Rejections over the prior art

Claims 1-8 have been rejected as either anticipated by or obvious over Pero et al. Applicants have cancelled claim 7 and amended claims 1 and 8 to recite that in the claimed method, cyclic adenosine diphosphate ribose (cADPR), or a functional analogue or derivative thereof, is the required treating agent in the composition administered to a patient in practice of the method of the invention. Applicants submit that nowhere in Pero et al. is the therapeutic agent recited in the claimed method mentioned or even suggested as a treating agent for an inflammatory condition. Therefore, Pero et al. cannot anticipate or make obvious the claimed invention and the art rejections have been overcome.

The Applicants submit that all claims in the application are in condition for allowance and such action is respectfully requested.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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